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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/786,937	01/22/97	BOUCHARD	P 235299/96001
			EXAMINER

HM11/0622

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ART UNIT	PAPER NUMBER

1654

DATE MAILED: 06/22/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 4/1/98
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 15-32 is/are pending in the application.
- ☐ Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 15-32 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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### DETAILED ACTION

1. Claims 15-20 and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diedrich et al. in view of Felberbaum et al.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Amendment***

The following is responsive to Applicant's amendment received April 1, 1998.

Claims 1-14 are cancelled without prejudice or disclaimer and claims 15-32 are added. Claims 15-32 are currently pending.

The following submitted hereinbelow is responsive to the amended claims and Applicant's remarks presented in the amendment received April 1, 1998.

### ***Claim Rejections - 35 USC § 112***

2. Claims 15-20 and 23-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 15, the term "low" is vague and indefinite. The metes and bounds of the patent protection desired is unascertainable. ✓

In claims 18 and 19, the phrases in ( ), render said claims unclear because one of ordinary skill in the art cannot ascertain whether the limitations in said phrase are or are not required in the claim. It is respectfully requested that said phrases be deleted or the ( ) themselves be deleted and the phrases properly incorporated into the claims. ✓

In claim 25, lines 1-2, the phrase "the LHRH antagonist" lacks antecedent basis. Said claim is dependent upon cancelled claim 7. Finally, claim 26 is vague and indefinite because it is also dependent upon cancelled claim 11. ✓

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3. Claims 17, 20, 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 17, the listed compounds do not have support in Applicant's specification, as originally filed.

In claim 20, line 2, the claimed amount of "0.1 to 1 mg" does not appear to have support in Applicant's specification, as originally filed. ✓

In claim 31, the Examiner is unable to find support for said claim in Applicant's specification and Applicant has not indicated where in the specification said limitation is found.

***Affidavit/Declaration***

Applicant's Declaration received April 1, 1998 has been considered but is not sufficient to overcome the reference to Felberbaum et al., European Journal of Obstetrics and Gynecology and Reproductive Biology, 61(2), 151-155.

The declaration serves to remove all co-authors in the reference except for Diedrich, K.; however, said reference is still available as prior art under 35 USC 102(a) because the Diedrich, K. article is still a publication by "another", i.e.

Diedrich, K. versus Diedrich **et al.** of the invention.

***Claim Rejections - 35 USC § 103***

Applicant's arguments and Declaration traversing the previous rejection under 35 USC 103(a), set forth in paragraph 5 of the office action mailed Dec. 1, 1997, have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed Dec. 1, 1997 with the following additional comment:

It is Applicant's position that the Declaration received April 1, 1998 is sufficient to overcome the Felberbaum et al. reference. With respect to the primary reference to Diedrich et al., Applicant argues that Diedrich does not disclose a method of treating infertility disorders wherein an improved dosage regime is employed, namely, lower dosages of .1 to

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.5 mg or single or dual dosages of 2 mg to 6 mg/day are administered to a patient in need thereof. Moreover, Applicant argues that the claimed method allows for suppression of LH without affecting FSH secretion, whereas Diedrich et al. discloses a method that suppresses LH surges but Diedrich teaches that patients are administered FSH at the beginning of treatment.

Said arguments have been considered but are not found to be persuasive.

As stated above, Applicant's declaration does not overcome the Felberbaum et al. reference. Said reference is maintained for reasons already of record. Concerning the Diedrich reference, It is the Examiner's position that Applicant's arguments with respect to the administration of Cetorelix in dosages of .1 to .5 mg or single or dual dosages of 2 mg to 6 mg/day, are not commensurate in scope with claims 15 and 21. Moreover, the Examiner maintains that Diedrich does disclose suppression of LH surges while also suggesting that under Cetorelix treatment, suppression of FSH is less pronounced. Please see page 790, second full paragraph. It is for the above reasons that the claims remain rejected.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Diedrich et al.

Diedrich et al. disclose a method of inducing ovarian stimulation in tubal sterile patients by administering a combination of exogenous gonadotrophins (HCG) and the LHRH antagonist Cetorelix to said patients. Cetorelix was administered at a dosage 3 mg daily starting on day 7 of the menstrual cycle. Please see the abstract; page 789, **Results**, first full paragraph; page 790, second column, first full paragraph; page 791, first column, third paragraph.

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Claim 22 is anticipated by Diedrich because Diedrich discloses administration of the same active agent, i.e. Cetorelix, to a patient using Applicant's claimed method steps. Accordingly, induction of ovulation between day 9 and 20 of the menstruation cycle is inherent.

**Conclusion**

Hence, claims 15-32 stand rejected.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on (703) 308-0254. The fax phone number for this Group is (703) 308-4242.

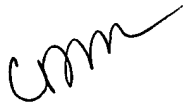
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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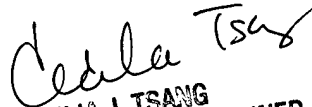
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CDM



June 21, 1998



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